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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,897	04/20/2000	David J. Roach	MLD-038	5776

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EXAMINER

QUAN, ELIZABETH S

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 10/17/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/556,897

Applicant(s)

ROACH ET AL.

Examiner

Elizabeth Quan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 16-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/30/2003 has been entered.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: vacuum line.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claims 1-4, 7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,207,031 to Adourian et al. in view of U.S. Patent No. 5,096,670 to Harris et al. and U.S. Patent No. 3,650,306 to Lancaster or U.S. Patent No. 5,432,085 to Warren et al.

Referring to claims 1-4, 7-15, Adourian et al. disclose a method and apparatus for processing a sample of biomolecular analyte using a microchip substrate. The system uses a robot (36,90) for moving a multifunctional device (42,100) with a plurality of ganged pipettors between at least one multi-well plate (34,104) containing samples and a loading station (32) with a plurality of microchips (120) (FIGS. 1 and 4; COL. 8, lines 45-63; COL. 10, lines 59-67; COL. 11, lines 1-10). The pipettors are "ganged" since they are assembled or operated simultaneously as a group as defined by Merriam-Webster Collegiate Dictionary. The robot with attached multifunctional device with a plurality of ganged pipettors delivers the sample from the multi-well plate to the sample ports (126) of the microchip (COL. 12, lines 41-47). The multifunctional device inserts the pipette tips through a corresponding plurality of apertures (132) defined by a tip guide (124) positioned in overlying registry with the sample ports of the

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microchip (FIG. 6; COL. 12, lines 35-61). The top surface of the microchip has additional openings (130) that provide access for electrophoresis electrodes and allow air to escape when material is injected into the channels (128), which extend within the microchip (COL. 12, lines 47-53). Adourian et al. disclose various embodiments of microchip substrates defining a plurality of microchannels communicating between opposed cathode and anode ports, wherein each microchannel includes a sample port and waste port communicating across a segment of the microchannel adjacent to the cathode port (FIGS. 8A-11B). Additionally, Adourian et al. disclose optically scanning separated samples with a CCD camera, which is located on a platform above the microchip and multi-well plate (FIG. 4; COL. 16, lines 59-COL. 17, line 12).

Adourian et al. do not specifically recite the use of movable first or second tracks for holding the microchip substrate and microtiter plate, respectively. However, Harris et al. disclose an automated patient sample analyzing instrument comprising a receiving substrate (216) mounted on a first frame connected to a movable first track (370) (FIG. 4; COL. 12, line 56-COL. 13, line 62). The system includes a microtiter plate (22) movably mounted on a second frame connected to a movable second track (20) (FIG. 4; COL. 9, lines 42-50). A gantry, which is positioned above the first and second tracks, carries a multi-functional device with a pipette wherein the open tip end has two electrodes (264) (FIG. 4; COL. 10, line 28-COL. 11, line 25). The multi-functional device with a pipette draws a sample from the plurality of wells of the microtiter plate, performs necessary dilutions, and transfers the diluted/undiluted sample to the plurality of ports of the receiving substrate (216) by horizontally moving from the microtiter plate (22) to align with a port of the receiving substrate (216) and lowering the pipette into the port of the receiving substrate (COL. 10, lines 28-43; COL. 10, line 59-COL. 11, lines 1-5).

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After pipette washing, the multi-functional device with a pipette horizontally moves to a well of the microtiter plate and lowers the pipette into the well to draw the sample (see COL. 13, lines 16-45). The pipette, first track, and second track are controlled by motor (225), motor (420), and motor (152), respectively (COL. 12, line 51-COL. 13, line 68). A platform positioned above the first track has a detector (546) and wires located on it (COL. 18, line 23-COL. 19, line 18). The system also comprises a feedback mechanism comprising optical and mechanical position sensors located on both the first and second frames (COL. 9, line 50-COL. 14, line 25). The system provides for continuous analysis since new microchip substrates can be continually placed on the conveyors, which move the microtiter plates and substrates downstream to the analyzers or waste receptacles (COL. 7, lines 20-39). The system has two processing lines, which allow two different tests to be performed simultaneously (COL. 3, lines 36-38).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included in the automated system of Adourian et al. the first and second moving tracks for holding the substrate and microtiter plate as taught by Harris et al. in order to increase throughput.

Adourian et al. disclose the use of electrokinetics to draw in samples. Harris et al. do not explicitly disclose what mechanism is behind the pipette drawing the samples. Providing a vacuum line in the multifunctional device with pipette(s) for drawing liquids is very well known. Harris et al. disclose an aspiration manifold with vacuum lines for removing liquids from wells in preparation of washing them (COL. 15, lines 37-64). Lancaster discloses a multi-functional device (100) with a plurality of ganged pipettors (27) and a vacuum line (144,140,142) creating a suction within each of the pipettors for simultaneously controlling the pick up and dispensing of

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liquid from the pipettors and accurately and precisely determining the exact microquantities of fluid to be picked up and dispensed (FIGS. 1 and 7; COL. 2, lines 6-20; COL. 4, lines 43-50; COL. 6, lines 63-65). Warren et al. disclose a multifunctional device with a plurality of pipettes and a vacuum line for providing sufficient suction for securely holding the pipette tips and removing waste from the substrate through the pipette tips (COL. 2, line 67-COL. 3, line 14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the multifunctional device of Adourian et al. to replace or supplement the electromagnetic device with a vacuum line as taught by Lancaster or Warren et al. for providing sufficient suction for securely holding the pipette tips, removing waste from the substrate through the pipette tips, simultaneously controlling the pick up and dispensing of liquid from pipettors, and accurately and precisely determining the exact microquantities of fluid to be picked up and dispensed.

7. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,207,031 to Adourian et al. in view of U.S. Patent No. 5,096,670 to Harris et al. and U.S. Patent No. 3,650,306 to Lancaster or U.S. Patent No. 5,432,085 to Warren et al., as applied to claim 4 above, and further in view of U.S. Patent No. 6,143,152 to Simpson et al.

Referring to claims 5 and 6, Adourian et al. in view of Harris et al. and Lancaster or Warren et al., as previously discussed above, fail to disclose a circuit board which has a first electrode terminal in communication with a first wire and sample terminals of the microchip substrate, a second electrode in communication with the cathode terminals of the microchip substrate, a third electrode terminal in communication with a waste terminal of the substrate and a fourth electrode in communication with an anode.

Simpson et al. disclose a microchip substrate having a plurality of microchannels (670,671) communicating between opposed cathode (674) and anode ports (660), the microchip further defining for each microchannel a sample port (676,678) and waste port (672) communicating across a segment of the microchannel adjacent the cathode port (FIGS. 9, 11, and 12; COL. 8, lines 13-42). Each port is connected to a voltage source via wires to cause the electrophoretic separation. Such a chip is considered conventional and well known in the art for its high-speed separation--reproducible, accurate, conveniently placed, robust, and sensitive (COL. 2, lines 34-43). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention made to have included in the apparatus and method of Adourian et al. in view of Harris et al. and Lancaster or Warren et al. a microfabricated capillary electrophoresis chip and circuit board as taught by Simpson et al. in order to perform chemical analysis on the electrophoresis chip automatically, since such a chip is considered conventional and well known in the art for its high-speed separation, reproducibly, and its ability to be accurately and conveniently placed.

Response to Arguments

8. Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection.
9. Applicant's arguments filed 6/30/2003 have been fully considered but they are not persuasive.
10. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so

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long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

11. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Harris et al. does provide teaching for the two movable tracks. Harris et al. cite that the instrument has two processing lines, which allow two different tests to be performed simultaneously (COL. 3, lines 36-38). Harris et al. expressly suggests that the two tracks create two processing lines, which allow two different tests to be performed simultaneously. This in itself is sufficient motivation. Additionally, since new microchip substrates and microtiter plates can be continually placed on the conveyors which move the microtiter plates and substrates downstream to the analyzers or waste receptacles, Harris et al. provides for continuous analysis (COL. 7, lines 20-39). Harris et al. implicitly suggests that the system allows for continuous analysis. In summary, the two tracks of Harris et al. provide for increased throughput. It is also noted that "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or **impliedly** suggest the claimed invention..." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). Therefore, Harris et al. provide

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a sufficient basis for a reasonable expectation of success since there would be increased throughput with two tracks.

12. Applicant argues that Adourian et al. and Harris et al. cannot be properly combined. Adourian et al. disclose an electrophoresis device with a loader for dispensing relatively small amounts of sample into relatively smaller ports, and Harris et al. disclose a device for assembling ELISA-type assays using much larger amounts of reagents dispensed into macroscale device. It is noted that Harris et al. provide for the teaching of the two tracks, and it does not matter whether smaller or larger samples are being dispensed. In fact, the size of the sample being dispensed is not affected by the larger system with tracks, motors, multifunctional devices, etc. Both pieces of prior art deal with robotic instruments in dispensing between two different substrates in a laboratory setting.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan
Examiner
Art Unit 1743


Jill Warden
Supervisory Patent Examiner
Technology Center 1700

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